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IMPLEMENTATION OF A MEASUREMENT UNCERTAINTY GUIDELINE FOR ISO/IEC 17025 LABORATORY ASSESSORS

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Abstract – This paper presents the implementation of a measurement uncertainty assessment guideline applicable to laboratory assessors. Measurement uncertainty is a relevant subject for all laboratories as well as for accreditation bodies since it consists in an elementary requirement for ISO/IEC 17025 accreditation. Therefore, it is crucial to assure that all technical assessors have an adequate level of knowledge about measurement uncertainty and know how to proper assess it. Researching the literature, it is possible to observe that all measurement uncertainty guidelines are focused on the laboratory perspective, to help them implement GUM's concepts. This work, on the other hand, was focused on the implementation of a new measurement uncertainty guideline intended exclusively to help laboratory assessors improve their knowledge about this subject and better prepare them to carry out laboratory assessments. The guideline was implemented in Rede Metrológica RS (RMRS), a regional accreditation body from southern Brazil. Simultaneously to this measurement uncertainty assessment guideline, it was also prepared a measurement uncertainty check-list to help assessors conduct their laboratory assessments. As a result, an improvement on the level of knowledge about measurement uncertainty was observed among RMRS assessors. The improvement was possible to verify through the application of written exams about measurement uncertainty, before and after the training on the new guideline. Exams showed the improvement of assessors' knowledge, demonstrating the relevance of this innovative work.

Keywords: measurement uncertainty, laboratory assessment, measurement uncertainty assessment guideline.

1. INTRODUCTION

At the present, there are many documents describing how to quantify measurement uncertainty, applying GUM's concepts and describing the relevance of this subject. Uncertainty is particularly useful in a conformity assessment, to quantify the probability of making a wrong decision [1; 2]. When uncertainty is not quantified in a proper manner, the interpretation of the result may also be prejudiced. Measurement uncertainty is a key factor for traceability and also demonstrates the laboratory quality level of measurement. With respect to the laboratory accreditation activity, measurement uncertainty is an elementary technical requirement in accordance ISO/IEC 17025 [3]. Therefore, relevant attention should be given to this issue.

During these years, many case studies were published in the literature concerning the application of GUM's concepts in a broad spectrum of calibration and testing fields, showing that this is not a trivial subject. In fact, some publications pointed out measurement uncertainty as one of the major difficulties on the implementation of ISO/IEC 17025 standard [4-7]. A study carried out by A2LA [8] indicated that measurement uncertainty is within the most deficient requirements among accredited laboratories. A2LA showed that deficiencies with respect to measurement uncertainty were cited at least in 30 % of all assessments [8]. This data demonstrates the need for improvement of laboratories and, on the other hand, emphasizes the importance of thoroughly knowing this subject when performing an assessment, in such a way to effectively assess the uncertainty presented by the laboratory.

Measurement uncertainty is a recurrent difficulty also recognized among Brazilian metrologists [4-7]. Taking in account this situation, this paper presents an innovative way to deal with this problem, aiming to better qualify laboratory assessors and help them conduct measurement uncertainty assessments. This improvement was achieved through the implementation of a new measurement uncertainty guideline for laboratory assessors, associated with a check-list for uncertainty assessment, implemented in Rede Metrológica RS (RMRS), a regional accreditation body from southern Brazil.

The first part if this paper briefly introduces RMRS and its activities. Subsequently, the methodology used to design and implement the guideline document for laboratory assessors and the respective check-list is presented, which was based on the PDCA cycle of improvement. After that, the results of the implementation of the document and conclusions are discussed.

2. CONTEXTUALIZING RMRS

Rede Metrológica RS (RMRS) – which is a Metrological Network for the State of Rio Grande do Sul – is a regional laboratory accreditation body located in southern Brazil. RMRS is a non-profit and non-governmental metrological association aimed to better qualify the metrological infrastructure in its State. It is also relevant to mention that RMRS is not the national official accreditation body of Brazil – which is Inmetro. Therefore, RMRS automatically recognizes Inmetro's accredited laboratories, with no need for further assessments.

Despite of that, RMRS has a considerable number of frequently assessed laboratories. Regarding its laboratory accreditation program, the total number of assessed laboratories per year has been constantly growing. Considering the last 3 years, there has been a 168 % growth in the total number of assessed laboratories. At the present, RMRS has over 135 frequently assessed and accredited laboratories in accordance to ISO/IEC 17025. In the same period, there was a 23 % increase in the total number of qualified assessors, totalizing 35 professionals that are contracted per assessment.

Although attending to a measurement uncertainty course is pre-requisite for all RMRS' assessors, there are still many doubts regarding practical and theoretical application of the GUM among the assessors, as well as how to satisfactorily evaluate this topic during a laboratory assessment. Therefore, RMRS had decided to give more attention to this subject and implement a guideline as well as a check-list to assist laboratory assessments particularly regarding measurement uncertainty evaluation and, therefore, increase assessors' knowledge about this subject.

3. UTILIZED METHODOLOGY

The design and implementation of the measurement uncertainty assessment guideline and its respective checklist were carried out following the steps of the PDCA cycle of improvement. The steps of this opportunity for improvement are presented in Figure 1.



Fig. 1. PDCA cycle for the measurement uncertainty guideline and the respective check-list

Step 'plan' consisted in collecting information and planning all actions needed to implement this improvement. The objective and methods are also established during this step. The objective, in this case, was to provide an opportunity for improving RMRS' laboratory assessment process, especially with respect to measurement uncertainty assessment. Toward that end, the method to achieve this objective was through the implementation of the measurement uncertainty assessment guideline and its particular check-list.

According to the results of the step 'plan', the measurement uncertainty guideline and the check-list for uncertainty assessment were elaborated. Following the PDCA cycle of improvement, this was done during step 'do', which consisted in the execution of what was previously planned.

Once the draft versions of the documents were prepared, they were submitted for analysis by a group of experts, which was formed by RMRS' representatives, as well as by invited uncertainty experts from Inmetro. This verification was carried out during step 'check', which aimed to evaluate the result of what was done with respect to what was planned before. This checking step verified whether the elaborated drafts: *i*) covered all topics previously identified as necessary; *ii*) were adequate in terms of written and layout presentation; *iii*) had the potential to satisfy assessors' needs. At the end of this step, the draft versions of the documents were considered as validated by the group of experts.

Finally, the step 'act' consisted in making all necessary adjustments and approving the documents. This step was divided into three stages, which were: *i*) making of the final adjustments to the documents; *ii*) approval of the documents; *iii*) dissemination of the documents within all assessors and laboratories. After concluding this step, the improvement could be considered implemented and standardized. So, a full PDCA cycle of improvement was implemented.

4. RESULTS

This section details the results from the design and implementation of the measurement uncertainty assessment guideline and its check-list. The following text is presented according to the steps of the PDCA cycle of improvement.

4.1. Step 'plan'

In the step 'plan', the data collected reinforced the need for a better qualification of assessors with respect to measurement uncertainty. The most deficient field identified in RMRS was testing assessors. All records of assessments performed by RMRS during the period of 2005-2007 were analyzed and significant differences between testing and calibration assessors were observed. Also, a form was sent to all assessors in the sense to map their major doubts and difficulties concerning measurement uncertainty. The result of this research pointed again that the most deficient area was testing.

From the total of 35 qualified assessors, 25 of them, or approximately 71 %, answered the inquiry, which shows an expressive number of respondents. From this group of respondents, 48 % are qualified to assess only in testing area, 36 % both in calibration and testing, simultaneously, and 12 % only in calibration. Also, 4 % are qualified only for quality management system assessment.

The initial inquiry provided an opportunity for assessors' self-evaluation of their knowledge about measurement uncertainty. It was asked for assessors to classify their knowledge about the GUM in accordance to the following categories: *i*) no knowledge at all about the GUM; *ii*) low level of knowledge; *iii*) reasonable knowledge; *iv*) good level of knowledge; *v*) full knowledge. Table 1 summarizes the answers to this question, stratifying by assessment area. For comparison purposes, results were also presented independently of the assessment area.

Table 1. Assessors' self-evaluation of their knowledge in accordance to GUM

How do you evaluate your knowledge abou measurement uncertaitny, according to the GUM?	% for assessors qualified in the following areas:			%
	Only Testing	Both Areas	Only Calibration	Independenti y of the area
No knowledge at all	0,0%	0,0%	0,0%	0,0%
Low level of knowledge	33,3%	0,0%	0,0%	16,7%
Reasonable knowledge	50,0%	40,0%	0,0%	33,3%
Good knowledge	16,7%	60,0%	42,9%	33,3%
Full knowledge	0,0%	0,0%	57,1%	16,7%

From these results, it can be seen that only 50 % of the assessors, independently of their area, claim to have a good or a full knowledge about measurement uncertainty according to the GUM. It is also evident that there is a clear difference between those who are qualified only for testing assessments and those who are qualified for calibration.

Subsequently, assessors' main doubts about measurement uncertainty were identified in the inquiry. The responses were grouped into the categories shown in Table 2. The percentages presented below were calculated considering the occurrence of each specific question, divided by the total number of questions in each area of assessment.

Table 2. Assessors' main doubts about measurement uncertainty

	% for assessors qualified in the following areas:			%
Assessors' Doubts	Only Testing	Both Areas	Only Calibration	y of the area
What should be assessed in terms of uncertainty and the evidences	32%	33%	20%	30%
Identification of uncertainty components	26%	0%	40%	26%
The method for expressing measurement uncertainty	16%	33%	20%	19%
Aplication in specific fields, such as chemical and microbiological tests	16%	0%	20%	15%
Practical examples	11%	33%	0%	11%

It is noteworthy that most of the doubts were from testing assessors (70%), which can indicate a possible greater deficiency among these assessors. The greatest doubt concerned what should the assessor verify and what evidences could be considered as satisfactory when assessing measurement uncertainty. One particular doubt was related to the identification of uncertainty components. Indeed, this is a frequent cause of disagreement during laboratory assessments. In the authors' opinion, accreditation bodies should strive to standardize uncertainty components, in such a way to clearly specify in their accreditation criterion documentation all relevant uncertainty components required in the major fields of testing and calibration. If they do so, then disagreement between assessors and assessed laboratories may probably be reduced, since this information should be of public access.

After concluding the inquiry, historical data from all records of assessments performed by RMRS during the period of 2005-2007 were analyzed. Results showed, again, significant differences between testing and calibration assessors. The results highlighted the necessity for an action aiming to improve assessors' level of knowledge about measurement uncertainty, taking particular attention to the testing area, which was the one that presented a greater number of assessors' doubts and lower level of knowledge in uncertainty.

Concluding the planning step, reference documents derived from the GUM were researched in order to gather information that could help assessors in conducting measurement uncertainty assessments. It is relevant to note that, with respect to this research, it was not possible to find any document that was addressed particularly to assessors. All references focused on the laboratory perspective.

On the stage of interviews, a group of experts in measurement uncertainty was consulted in order to identify a more comprehensive overview on uncertainty assessment activities, therefore, helping the identification of assessors needs. This group was formed by RMRS' representatives, as well as invited experts from Inmetro. Gathering all information previously obtained, the last stage of the step 'plan' was the consolidation of the main topics of the documents that was to be prepared. These topics were defined considering assessors' doubts as well as the expert's suggestions and the literature documents consulted previously.

4.2. Step 'do'

Following the PDCA cycle of improvement, during the step 'do', the draft version of the documents were prepared by the authors in accordance to the topics previously agreed with the group of experts. As the aim of the guideline was to better qualify RMRS assessors, prioritizing their doubts and difficulties, the document included a brief review of the major concepts of the GUM, as well as a flow-chart summarizing all steps for the quantification of measurement uncertainty. Since a frequent assessors' doubt detected during the research was related to the knowledge about sources of uncertainty, a list of common uncertainty components in calibration and testing fields was included in the guideline, covering many common testing and calibration cases. This table was prepared gathering information from many different references, described in [2; 9-19].

Simultaneously to the elaboration of the guideline, the check-list for uncertainty assessment was also prepared.

This check-list included a list of all topics that shall be verified during a measurement uncertainty assessment.

4.3. Step 'check'

During the step 'check', the guideline and the check-list drafts were submitted for analysis by the already mentioned group of experts. Comments and suggestions were sent through e-mail during a period of approximately one month.

4.4. Step 'act'

Taking into account all comments and suggestions received regarding the drafts, final adjustments were made and the guideline and its respective check-list were formally approved by RMRS' board. After that, the documents were published in RMRS' website, for public access. Download can be found in the references [20; 21]. It is relevant to mention that, at the present, only the Portuguese version is available for download.

As a result of the implementation of the referred documents, an improvement on the assessors' level of knowledge about measurement uncertainty was achieved. To measure this improvement, written exams were applied within RMRS' technical assessors before and after a training section about the new documents.

Exams were anonymously treated, individually answered and with no consultation allowed. The exams covered the following topics: *i*) fundamentals of measurement uncertainty according to the GUM; *ii*) uncertainty budget practical calculation; *iii*) laboratory uncertainty assessment issues. All questions received the same weight and the final score was presented in a 0 to 100 scale. Assessors had 30 minutes to answer each exam. Table 3 presents the average scores before and after the training section.

Table 3. Written exams average scores before and after the training

Parameter	Score before the training	Score after the training	
Average - \overline{X}	59,3	78,2	
Standard deviation - S	10,9	10,9	
Number of respondents - N	21	21	

It can be seen through Table 3 a significant improvement on assessors' scores at a level of significance of 5 % (pvalue of 2×10^{-6}). Therefore, exams showed the improvement of assessors' knowledge, demonstrating the relevance of this work.

Analysing the most frequent mistakes observed during the exams, it was possible to observe that the main causes of confusion were related to verification of uncertainty budgets, expression of uncertainty, fundamentals and concepts, as well as the conformity assessment activity using uncertainty information. Table 4 summarizes the main mistakes done by assessors during the exams. The referred table presents questions with the lowest percentages of correct answers from the initial and final exams. Table 4. Main causes of mistake during initial and final exams

Subject	Exam Moment	Main Cause of mistake	% of correct answers
UB	В	Incorrect calculation of sensitivity coefficients	14 %
EU	В	Presentation of the measurement range and its best measurement capability: did not observe the definition of one unique best measurement capability for each measurement range.	17 %
EU	А	Measurement uncertainty presented with more than 2 significant figures.	17 %
FC	В	Did not recognize a limitation that the Welch- Satterhwaite formula can produce incorrect results when dealing with correlated input quantities.	19 %
FC	В	Wrong concept that systematic errors should be included in uncertainty budgets. Instead, systematic errors should be correct whenever possible. The mistake could also indicate confusion between the concepts of uncertain and error.	24 %
UB	В	Divided a repeatability standard deviation obtained from historical data by N , where N was stated to be the sample size from this historical data. Instead, N should be the sample size of the current measurement, not the historical data.	24 %
FC	А	Fundamental confusion between sensibility coefficients and divisors utilized to obtain standard uncertainties.	29 %
CA	A	Incorrect interpretation of a result in a conformity assessment, when uncertainty is affecting the conformity with a specification. Incorrect calculation of the probability of making a wrong decision under these circumstances.	38 %

The notation utilized in Table 4 for the subject was:

UB = verification of uncertainty budget;

EU = expression of uncertainty;

FC = fundamentals and concepts;

CA = conformity assessment

For the column of the exam moment, 'B' stands for the exam before the training and 'A' the exam after the training section with RMRS' assessors.

Eventually, the correction of exams was sent individually to all assessors, aiming a better clarification of their possible doubts. After the implementation of this improvement, it is relevant to mention that Rede Metrológica RS is still monitoring its assessors' doubts through periodic workshops, where frequent assessment difficulties and assessors' doubts are discussed with the group and properly treated.

5. CONCLUSIONS

This paper presented the implementation of a new measurement uncertainty assessment guideline and a checklist for uncertainty assessment intended to better qualify laboratory assessors and help them conduct technical assessments of measurement uncertainty. These documents were implemented in Rede Metrológica RS (RMRS), a regional accreditation body of southern Brazil.

These new documents provided a clear and direct guidance on measurement uncertainty assessment and

improved RMRS assessors' level of knowledge about the subject.

To measure this improvement, written exams were applied within RMRS' technical assessors before and after a training section about the new documents. Table 3 showed a significant improvement on assessors' scores, after the training on the new documents (p-value of 2×10^{-6}).

It is also relevant to note that the referred documents are available for download [20; 21], observing that only a Portuguese version is currently presented.

Eventually, the documents should not be considered as a definite production. Therefore, any suggestions for improvement are welcome and can be addressed directly to the authors or to Rede Metrológica RS.

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